K091258

Extrafix External Fixation System
510(k) Summary

Device Manufacturer:	QFX Technologies 8275 Tournament Drive, Suite 160 Memphis, TN 38125
Submission Date:	July 15, 2009
Contact Person:	Steve Miller Tel: 1-831-331-5675 Fax: 1-831-440-9837
Proprietary Name:	Extrafix External Fixation System
Common Name:	External Fixation Frame Components
Classification regulation:	888.3030 Single/multiple component metallic bone fixation appliances and accessories, 888.3040 Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Product Codes:	KTT and JDW

JUL 2 4 2009

Device Description and Intended Use:
The Extrafix External Fixation System includes various elements designed to build a fixator construct. The system includes clamps, posts, bars, and fixation pins.

The Extrafix External Fixation System is indicated for use in construction of an external fixation frame for treatment of long bone (foot, femur, and tibia) and pelvic fractures that require external fixation. Specifically, the system is intended for:

- Temporary stabilization of open or closed acute fractures with soft tissue injuries;
- Definitive stabilization of open or closed fractures where open or alternative closed treatment is undesirable or otherwise contraindicated;
- Stabilization of fractures in the context of polytrauma;
- Temporary or definitive stabilization of certain pelvic fractures or pelvic ring injuries;
- Arthrodesis and osteotomies with associated soft tissue problems;
- Stabilization of limbs after removal of total joint (knee, and ankle) arthroplasty for infection or other failure;
- Neutralization of fractures stabilized with limited internal fixation;
- Stabilization of non-unions; and
- Intraoperative temporary stabilization tool to assist with indirect reduction.

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Predicate Devices:
The Extrafix External Fixation System is similar to several predicates including the following:

- Stryker Hoffmann II MRI External Fixation System (K053472);
- Synthes Large External Fixation Clamps- MR S (K031428); and
- Smith & Nephew Jet-X Unilateral Fixator (K994143).

Technological Characteristics
The Extrafix External Fixation System was characterized and evaluated according to the requirements outlined in ASTM F1541-02 (2007), Standard Specification and Test Methods for External Fixation Devices and the FDA Reviewers Guidance Checklist for Orthopedic External Fixation Devices.

Substantial Equivalence Information:
The Extrafix External Fixation System is similar to legally marketed devices listed previously in that they share similar indications for use and incorporate similar technological characteristics. All evaluations determined that the Extrafix External Fixation System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

QFX Technologies, Inc.
% M Squared Associates, Inc.
Mr. Marcos Velez-Duran
President
901 King Street, Suite 200
Alexandria, Virginia 22314

JUL 24 2009

Re: K091258
Trade/Device Name: Extrafix External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT, JDW
Dated: April 28, 2009
Received: April 29, 2009

Dear Mr. Velez-Duran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehrp for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091258

Indications for Use Statement

510(k) Number: To be assigned

Device Name: Extrafix External Fixation System

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- Intraoperative temporary stabilization tool to assist with indirect reduction.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonda J for MVM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091258